Maxillary sinus augmentation with biphasic calcium phosphate: a clinical and radiographic study

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Maxillary sinus augmentation with biphasic calcium phosphate: a clinical and radiographic study

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감사의 글

이 논문의 연구계획에서부터 완성에 이르기까지 학문적 기틀을 잡아 주시고, 논문이 완성되기까지 부족한 저를 항상 격려해 주시고 아버지와 같은 사랑과 관심으로 이끌어 주신 최성호 교수님께 깊은 감사를 드립니다. 그리고 언제나 따뜻한 관심과 조언을 아끼지 않으셨던 채중규 교수님, 조규성 교수님, 김창성 교수님, 정의원 교수님께도 감사 드립니다.

본 논문의 실험 과정 내내 많은 도움을 주시고 부족한 후배의 학문적 성취를 이끌어 주신 이중석, 박정철 교수님과 치주과 모든 의국원들에게도 감사를 드립니다.

끝으로 항상 기도로 제 앞날을 염려해 주시고 아낌없는 사랑으로 지원해 주신 양가 부모님께 감사의 말씀을 드리며, 부족한 남편을 한없이 이해해 주고 사랑해 준 아내에게 이 논문을 바칩니다. 오늘의 작은 결실에 자만하지 않고 항상 겸손한 자세로 꾸준히 노력하는 좋은 모습을 보이도록 하겠습니다.

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저자 씀

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ABSTRACT

Maxillary sinus augmentation with biphasic calcium phosphate: a clinical and radiographic study

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The aim of this study was to evaluate 3.5 years-cumulative survival rate of implants placed on augmented sinus using Osteon®, a bone graft material, and to assess the height of the grafted material through radiographic evaluation. Twenty patients were treated with maxillary sinus augmentation and 45 implant fixtures were installed simultaneously or after 6 months healing period. The height of the augmented sinus and the loss of marginal bone were measured by panoramic and intraoral radiographs immediately after augmentation and up to 42 months (mean 19.4) subsequently. Changes in the height of the sinus graft material were calculated radiographically. The cumulative survival rate was 95.56% in all 45 implants. Additionally, normal healing process without any complication was observed in all patients. The original sinus height was mean 4.3 mm and the augmented sinus height was mean 13.4 mm after the surgery. The mean marginal bone loss till 42 months was 0.52±0.56mm. The reduced height of Osteon® was 0.83±0.38 mm and it did not show significant correlation with the follow up periods (P=0.102). There were no statistically significant differences in reduced height of Osteon® according to the simultaneous/delayed implantation (P=0.299) and particle size of Osteon® (P=0.644). It can be suggested that Osteon® may have predictable result when it was used as a grafting material for sinus floor augmentation.

Key Words: maxillary sinus, dental implants, survival rate

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I. Introduction

One of the necessary requirements for dental implant is to ensure with a moderate amount of bone to place an implant with appropriate length and diameter. The loss of alveolar ridge due to trauma, periodontal disease, or the failure of endodontic treatment, however, may make it difficult to place the implant on ideal place with proper esthetics and function. Especially in the maxillary posterior area, it is known to be difficult and to have a low success rate because of the poor bone quality. Moreover, the posterior edentulous maxilla has represented a challenge for clinicians owing to the resorption of alveolar ridge and pneumatization of maxillary sinus.

This has led to the development of bone augmentation technique, the onlay bone graft and the sinus augmentation. Sinus augmentation via lateral window osteotomy has been routinely performed in the last few years and has been regarded as a predictable

procedure (Chiapasco et al., 2008; Jensen et al., 1998; Pjetursson et al., 2008; Wallace and Froum, 2003). However, the choice of the bone graft material is still under discussion.

The use of autogenous bone in sinus augmentation has been regarded as a superior method because in that reproducible healing mechanism of osteogenesis, osteoinduction, and osteoconduction. Nevertheless, there are some limitations e.g. the needs of additional surgical sites and rapid resorption rate when the autogenous bone was used as a sinus grafting material (Hallman et al., 2002; Johansson et al., 2001; Misch and Dietsh, 1993). Therefore, the use of synthetic bone has been recently appraised for its biocompatibility and volume maintenance capacity (Dalkyz et al., 2000; Kim et al., 2009).

Various synthetic materials have been developed for use in maxillary sinus augmentation to allow bone ingrowth and to prevent sinus pneumatization after grafting. Among them, the mixture of hydroxiapitite (HA) and beta-tricalcium phosphate (β-TCP) has been studied vigorously as a new alloplastic material (Daculsi et al., 1989). The HA can play an osteoconductive role due to its appropriate space maintenance capacity, but has low osteogenetic property. While β-TCP, with its good biocompatibility, has been used as a substitute of autogenous bone (Gauthier et al., 1998; Karabuda et al., 2001). In this point of view, mixing adequate ratios of HA and β-TCP allowed to control the resorption rate without distorting its osteoconductive property (Nery et al., 1992; Yamada et al., 1997a, 1997b).

Osteon® (Dentium, Seoul, Korea) is synthetic material containing 70% HA and 30% β-TCP. It has a porous structure which can accelerate new bone ingrowth and maturation

(Fig. 1). Two different particle sizes of Osteon® have been used (0.5-1.0 mm and 1.0-2.0 mm). In several previous studies, Osteon® was regarded as a suitable sinus augmentation material based on the histologic analysis (Kim et al., 2008). Moreover, we have precedingly reported that the volume maintenance of grafted Osteon® and implant success rate as a pilot study (Cha et al., 2010). In that study, the grafted material was well maintained in sinus and decreased slightly over 1 year (0.05 mm/month). It can be suggested that Osteon® may have predictable result when it was used as a grafting material for sinus floor augmentation.

The aim of the present study was to evaluate cumulative survival rate (CSR) of implants placed on augmented sinus using Osteon®, and to assess resorption rate of the grafted material radiographically with increased sample size and statistical power as an extension of our previous studies.

II. Material and methods

This study was approved by the Institutional Review Board of Yonsei University College of Dentistry (Approval No. 5-2008-3). A total 45 implants were placed in 20 maxillary sinuses of 20 patients (8 males, 12 females, mean age 57.2±11.3 years) with the condition of having under 5mm of residual alveolar bone height, using sinus augmentation technique via lateral window osteotomy (Zitzmann and Scharer, 1998). All implants were maintained with at least 6 months of prosthetic loading time. Patients' exclusion criteria were: (1) heavy smoker (more than 20 cigarettes per day), (2) debilitating systemic disease like uncontrolled diabetic mellitus (3) sign and symptom of maxillary sinus disease (4) active periodontal disease involving the residual dentition.

Five implants were from Branemark System-MKIII TiUnite (NobelBiocare, Gotenborg, Sweden); 12 implants were from Xive (Dentsply Friadent, Mannheim, Germany), 5 implants were from Astra (Astra Tech, Mölndal, Sweden), 6 implants were from Osstem GSII (Osstem implants, Busan, Korea), 17 implants were from Implantium (Dentium, Seoul, Korea). All implants were placed in either 1 or 2 stage surgery. The timing of implantation was determined, depending on the primary stabilization of implants. In the 2 stage approach, implantation was performed 6 months after the augmentation of the maxillary sinus.

Mixture of 2 different types of Osteon® in a 1:1 ratio was used in 10 patients, while only larger particle size of Osteon® was used in the other 10 patients. The quality of bone

was evaluated according to the Lekholm and Zarb's classification during the surgical procedure (Zarb and Zarb, 1985). Most of the examined subsinus ridges were composed of bone with poor quality (type III and IV). The general information of cases is presented in Table 1.

1. Surgical technique

A modified Caldwell-Luc sinus augmentation was performed under local anesthesia (2% lidocaine hydrochloride–epinephrine 1:100,000, Kwangmyung Pharmaceutical) (Boyne and James, 1980; Kent and Block, 1989). In brief, the surgical area was prepared via elevation of full thickness muco-periosteal flap. Osteotomy was performed at the lateral surface of the sinus wall using diamond round bur and piezoelectric device (Piezosurgery, Mectron, Carasco, Italy) and the sinus membrane was carefully lifted. The sinus cavity was then packed with Osteon®, and the lateral window was covered by an absorbable sponge (Collatape®, Zimmer dental, USA). The muco-periosteal flap was repositioned and sutured with absorbable suture material (Monosyn 4.0 Glyconate Monofilament, B. Braun Tuttlingen, Germany), (Vicryl 5.0 Polylactim, Johnson and Johnson, U.S.A). The prosthodontic procedure was completed after a mean healing period of 6-12 months.

2. Implant survival rate

The 42 months CSR for implants was evaluated using life table analysis (Cutler and Ederer, 1958). The success criteria for implants presented by Buser et al. was used (Buser et al., 1990).

3. Radiographic analysis

The radiographic analysis was performed by panoramic radiographs and intraoral radiographs using software (Starpacs®, Infinitt, Seoul, Korea). All the values were calibrated precisely based on the length of implant fixture and these were undertaken double check by a single investigator. At least 2 consecutive panoramic radiographs were taken one immediately after the sinus augmentation, the other 1 year after the surgery. Additional radiographs were obtained every 6 to 12 months through the follow up protocol. The linear measurements taken from radiographs were described below (Hatano et al., 2004), (Fig. 2). The origianl alveolar bone heights (OAH) prior to the surgery (Block et al., 1998), from the alveolar crest to the base of sinus were measured (Table 1). The augmented sinus heights (ASH) were measured from the 1st bone to implant contact points to the base of the maxillary sinus, which was elevated with Osteon® at mesial and distal aspects of implants. The volume of marginal bone loss (MBL) was obtained compared with the intraoral radiographs immediately taken after the surgery and 1 year

postoperatively. The reduced height of Osteon® (RHO) was calculated based on the change of ASH and MBL.

4. Statistical analysis

Individual mean values were calculated. Differences in RHO according to the timing of implantation and the type of Osteon® were analyzed using the independent *t*-test. A one way analysis of variance was used to evaluate the difference of RHO according to the implant sites. The post-hoc Scheffe test was used to evaluate the differences between groups. A *P* value of <0.05 was considered significant. Correlation between the RHO and follow up period were determined by Spearman's test. SPSS version 12.0.0 (LeadTech, Chicago, IL, U.S.A) was used for all of the statistical analysis.

III. Results

1.Implant survival rate

No complications including wound dehiscence, sinus membrane perforation were observed in all patients. 2 of the 45 implants were removed between implantation and the follow up period (case 2, $I_{16,\ 17}$). All loss of implants was occurred prior to prosthetic loading. Both were successfully restored by wider diameter implants. The 0 to 6 month CSR was 95.56% and this value continues to 42 months (Table 2).

2.Radiographic analysis

The mean follow up period of implants after the sinus augmentation was 19.4 months (range: 12-42 months). The original sinus height was mean 4.3 mm (range: 2.5-5.8 mm) and the augmented sinus height was mean 13.4 mm (range: 9.81-18.1 mm) after the surgery. The mean crown/implant ratio was 1.19±0.24 mm which was relatively higher than natural molar. The marginal bone loss till 12 months was measured 0.29±0.42 mm and till 42 months 0.52±0.56 mm. The RHO in 1-year postoperatively was 0.83±0.38 mm, in 42 months postoperatively was 0.88±0.39 mm (Table 3). No significant correlation was noted between the RHO and follow up periods by Spearman's test (P=0.102). There

were no statistically significant differences in reduced height of Osteon® according to the simultaneous/delayed implantation (P=0.299; Table 4) and particle size of Osteon® (P=0.644; Table 5). In addition, no significant difference in the RHO was observed following the site of implantation (P=0.527; Table 6).

IV. Discussion

An ideal material for maxillary sinus augmentation should provide biocompatibility to allow bone ingrowth and space maintaining property to prevent sinus pneumatization (Block et al., 1998). In the results of present study, the grafted Osteon® was well maintained in sinus and decreased slightly over 3.5 years of time period demonstrating that it is a clinically suitable material for sinus augmentation.

Some volumetric loss of grafted material is unavoidable because of the air pressure from respiration in the maxillary sinus regardless of the type of material used (Chanavaz, 1990; Chanavaz et al., 1990; Jensen et al., 1998). Therefore, the change in the height of grafted material is an important factor for implant stability.

Previous studies about the loss of grafted material have been controversial. Hatano et al. used autogenous bone and xenogenous bone mixed at a ratio of 2:1 for sinus augmentation with simultaneous implant placement and evaluated the resorption rate (Hatano et al., 2004). They reported that a statistically significant resorption was occurred after 2-3 years, and the maxillary sinus floor was observed at the similar or slightly below level of the implant apex. On the other hand, Maiorana et al. evaluated the resorption rate after 4 years of maxillary sinus augmentation using synthetic bone graft material (hydroxyapatite and collagen). The survival of implant was 97% and the grafted material remained steady showing 0.5-1 mm resorption height (Maiorana et al., 2006). Generally, it was reported that the resorption rate is influenced by the various kind of graft materials

(Jensen et al., 1998). The resorption rate was 1.76 mm in autograft, 2.09 mm in allograft (free-dried demineralized bone), and 0.96 mm in alloplast (hydroxyapitite).

The maxillary sinus cavity is a kind of contained defect surrounded by sinus basal bone and the schneiderin membrane, thus it has excellent healing potential even without bone graft materials. In this point of view, the long-lasting synthetic and xenogenic bone materials are considered to be better choice in terms of the material resorption.

Two out of 45 implants were removed in this study before prosthetic loading, so it can be regarded as an early failure. It seems that excessive hematoma causes the formation of exuberant granulation tissue which can be detrimental to initial osseointegration. The overall CSR was 95.56% and this result was comparable with other studies despite the small sample size (Chiapasco et al., 2008; Jensen et al., 1998; Pjetursson et al., 2008; Wallace and Froum, 2003).

The reduced volume of the Osteon® was increased compared to our previous report (0.48 mm resorption in 13 months) (Cha, 2010). No significant difference of the reduced volume of the Osteon® was observed according to the timing of implantation. From our previous studies, it was reported that the largest amount of Osteon® resorption occurred in the 1st molar area and the augmented sinus membrane was changed from a convex shape to a flat shape. In this study, however, there was no correlation between the area of the implantation and the resorption rate.

Interestingly, the resorption of Osteon® was occurred regardless of the flow of time. In most of other papers, it was found that the graft materials might undergo gradual

resorption and pneumatization by time (Hatano et al., 2004; Jensen et al., 1998). Hieu et al. radiographically evaluated the changes in height of the xenogenic materials (Bio-Oss®, Geistlich, OCS-B®, Nibec) after maxillary sinus augmentation by 2 years. These studies reported that significant material resorption has been taken place depending on the flow of time (Hieu et al., 2010). Nonetheless, it could be assumed that many other factors e.g. the air pressure in the maxillary sinus, the form of augmented material and the density of the grafted material are more important than the time flow. Therefore, it is considered that resorption rate of the grafted material is affected by the host's environment. This would be expected to be clarified in the further study.

Two dimensional Panoramic radiographs have been used to evaluate the grafted material and its relationships with implants (Hatano et al., 2004; Kahnberg et al., 2001; Keller et al., 1994). Recently, the study utilizing computed-tomography and magnetic resonance imaging was reported to assess the grafted sinus floor and this showed more accurate results of the volumetric change (Gray et al., 2001). However, in the present study, we used only 2-dimensional images, thus further study would be needed through 3-dimensional images for more accurate volumetric measurement of Osteon®.

V. CONCLUSION

Within limitation of this study, it can be suggested that Osteon® may have predictable result when it was used as a grafting material for sinus floor augmentation since its exellent osteoconductive property.

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Legends

Table 1. Case summary.

Table 2. Life table analysis.

Table 3. Radiographic analysis (mean±standard deviation).

Table 4. Differences according to the timing of implantation (mean±standard deviation).

Table 5. Differences according to the type of material (mean± standard deviation).

Table 6. Differences according to the site of implants (mean± standard deviation).

Figure 1. Scanning electron microscope image of Osteon®

Figure 2. Schematic drawing illustrating the linear measurement taken from radiographs. (A) Immediately after the sinus augmentation, (B) 1-year after the sinus augmentation. MBL: marginal bone loss, C: crown length, I: implant fixture length, OAH(m): mesial original alveolar bone height, OAH(d): distal original alveolar bone height, ASH(m): mesial augmented sinus height, ASH(d): distal augmented sinus height.

Tables

Table 1. Case summary

Case	Age/ Sex	Area	System	Diameter	Length	1 or 2 stage	Original bone height (mm)	Dose of Osteon(cc)	Type of OSteon	Bone quality	F/U (month)
1	54/F	15	Branemark	4	10.5	simultaneous	4.3	3	S/L	IV	30
		16	Branemark	5	11.5	simultaneous	2.5			IV	30
2	75/F	15	Branemark	4	11.5	simultaneous	5.0	2.5	S/L	III	42
		16	Branemark	4	11.5	Delayed	2.9			IV	29
		17	Branemark	4	11.5	Delayed	3.5			IV	29
3	71/M	26	Implantium	3.8	10	Delayed	5.7	2	S/L	III	16
		27	Implantium	3.8	10	Delayed	2.5			IV	16
4	64/F	25	Xive	3.4	9.5	Simultaneous	5.5	1.5	S	III	18
		27	Xive	3.8	9.5	Simultaneous	3.2			IV	18
5	47/F	15	Xive	3.8	9.5	Simultaneous	5.6	1.5	S	III	29
		16	Xive	4.5	9.5	Simultaneous	5.5			III	29
		17	Xive	4.5	9.5	Simultaneous	3.3			III	29
6	54/M	16	Implantium	4.3	8	Simultaneous	5.0	2.5	S/L	III	19
		17	Implantium	4.3	8	Simultaneous	3.5			III	19
7	59/M	26	Implantium	4.8	12	Simultaneous	4.8			III	17
		27	Implantium	4.8	10	Simultaneous	4.9			III	17
8	47/F	25	Astra	4	9	Simultaneous	5.8	2	S/L	III	18
		26	Astra	4	9	Simultaneous	4.3			IV	18
		27	Astra	4	9	Simultaneous	5.4			IV	18
9	70/M	25	Osstem GSII	4	11.5	Simultaneous	5.6	1.5	S/L	III	21

Case	Age/ Sex	Area	System	Diameter	Length	1 or 2 stage	Original bone height (mm)	Dose of Osteon(cc)	Type of OSteon	Bone quality	F/U (month)
		26	Osstem GSII	4	8.5	Simultaneous	4.0			III	21
		27	Osstem GSII	4	8.5	Simultaneous	4.7			III	21
10	77/F	15	Xive	3.4	9.5	Simultaneous	4.5	3	S	III	24
		16	Xive	3.4	9.5	Simultaneous	3.5			III	24
11	52/F	26	Xive	3.8	9.5	Delayed	3.8	1.5	S	III	18
12	52/F	26	Implantium	4.8	10	Delayed	3.2	1.5	S/L	III	15
		27	Implantium	4.3	10	Delayed	3.4			III	15
13	55/M	15	Osstem GSII	4	10	Simultaneous	4.8	1.5	S	III	20
		16	Osstem GSII	4	10	Simultaneous	3.7			III	20
		17	Osstem GSII	4.5	10	Simultaneous	3.6			III	20
14	41/M	16	Xive	3.8	9.5	Simultaneous	3.8	2	S	III	24
		17	Xive	3.8	9.5	Simultaneous	5.1			III	24
15	40/M	16	Astra	4	13	Delayed	4.7	2.5	S/L	III	17
		17	Astra	4	13	Delayed	5.7			III	17
16	45/F	16	Implantium	4.3	10	Delayed	2.5	2.5	S	II	12
		17	Implantium	4.3	10	Delayed	3.7			II	12
17	58/M	25	Implantium	4.3	8	Simultaneous	4.3	1.5	S	IV	12
		26	Implantium	4.3	8	Simultaneous	4.1			IV	12
18	74/F	25	Implantium	3.8	8	Simultaneous	5.4	1.5	S	III	12
		26	Implantium	4.3	8	Simultaneous	3.2			III	12
		27	Implantium	3.8	8	Simultaneous	5.6			III	12
19	53/F	16	Xive	4.5	9.5	Simultaneous	3.7	4	S	III	12
		17	Xive	4.5	9.5	Simultaneous	3.6			III	12
20	56/F	25	Implantium	4.3	10	Simultaneous	4.4	2.5	S	II	12
		26	Implantium	4.3	10	Simultaneous	3.8			II	12

S: small particle, L: large particle, f/u: follow up.

Table 2. Life table analysis.

Time (month)	Implant at risk	Failure during interval	Interval survival (%)	CSR (%)
0~6	45	2	95.56	95.56
7~12	43	0	100	95.56
13~18	32	0	100	95.56
19~24	18	0	100	95.56
25~30	6	0	100	95.56
31~36	1	0	100	95.56
37~42	1	0	100	95.56

CSR: cumulative survival rate.

Table 3. Radiographic analysis (mean±SD).

	C/I ratio	MBL (mm)		RHO (mm)	
		Time (months)		Time (months)	
		0-12	0-42	0-12	0-42
Mean	1.19 ± 0.24	0.29 ± 0.42	0.52 ± 0.56	0.83 ± 0.38	0.88 ± 0.39

MBL: marginal bone loss, C/I ratio: crown/implant ratio, RHO: Reduced height of Osteon®.

Table 4. Differences according to the timing of implantation (mean±SD).

	Simultaneous (n=34)	**Delayed (n=11)**	**P value (<0.05)**
RHO (mm)	0.80 ± 0.40	0.91 ± 0.30	0.299

Table 5. Differences according to the type of material (mean±SD).

	S (n=22)	**S/L (n=23)**	**P value (<0.05)**
RHO (mm)	0.81 ± 0.43	0.85 ± 0.33	0.644

S: small particle size (0.5-1mm), L: large particle size (1-2mm).

Table 6. Differences according to the site of implants (mean±SD).

	P2 (n=8)	**M1 (n=22)**	**M2 (n=15)**	**P value (<0.05)**
RHO (mm)	0.92 ± 0.42	0.85 ± 0.34	0.75 ± 0.42	0.527

P2: the 2nd premolar.

M1: the 1st molar.

M2: the 2nd molar.

Figures

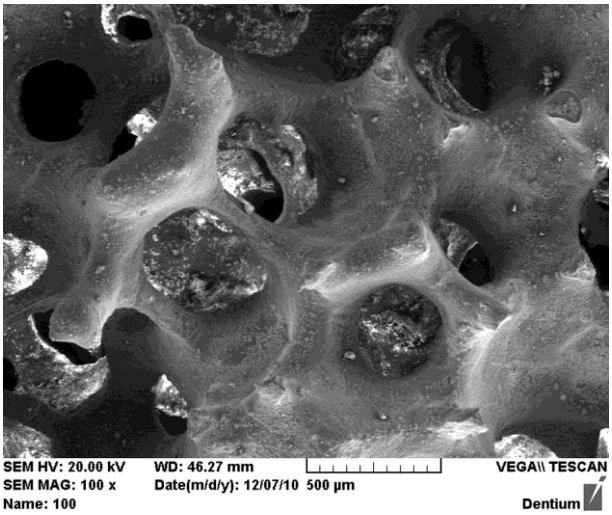

Figure 1. Scanning electron microscope image of Osteon®

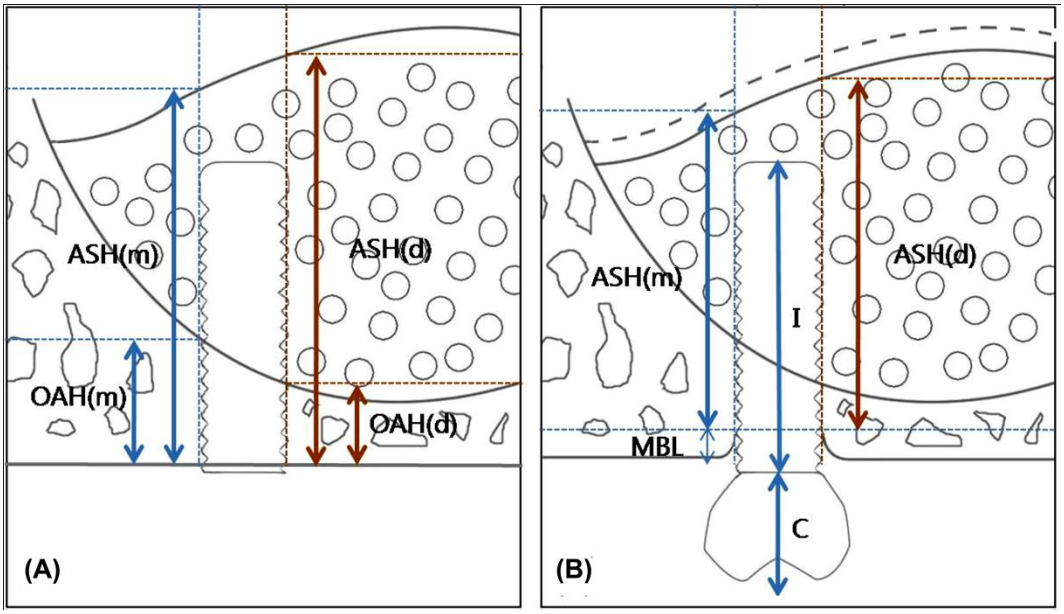

Figure 2. Schematic drawing illustrating the linear measurement taken from radiographs. (A) Immediately after the sinus augmentation, (B) 1-year after the sinus augmentation. MBL: marginal bone loss, C: crown length, I: implant fixture length, OAH(m): mesial original alveolar bone height, OAH(d): distal original alveolar bone height, ASH(m): mesial augmented sinus height, ASH(d): distal augmented sinus height.

국문요약

합성골 이식재인 Osteon®을 이용한 상악동 거상술 -임상적, 방사선 계측학적 연구

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상악동 거상술을 시행할 때 사용할 골이식재의 선택은 임상가에게 있어서 고민이 되는 부분이다. 골이식재로서 자가골은 골형성능 및 골유도능을 갖춘 최상의 골이식재로 평가받지만, 상악동에 적용 시 빠른 흡수 양상을 보인다. 또한 자가골 채득을 위해 제 2 의 수술부위가 필요한 점, 채취량의 한계로 인해 최근엔 상악동 골이식재로 합성골의 사용이 대두되는 추세이다. 본 연구에서는 합성골 이식재인 Osteon®을 단독으로 적용하여 상악동 거상술을 시행한 20 명의 환자, 45 개의 임플란트를 대상으로 3.5 년의 재내원 기간을 두고 임상적, 방사선 계측학적 방법을 통해 그 부위의 생존율과 골흡수율을 조사하였다. 방사선학적 계측은 파노라마 방사선 사진을 이용하였고 결과는 다음과 같다. 1. 임플란트의 누적 생존율은 95.56 %이다. 2. 모든 환자에서 임상적으로 정상적인 치유과정을 보였다. 3. 수술 전 치조골의 높이는 평균 4.3 mm 였고, 수술 후 거상된 높이는

13.4 mm 였다. 4. 42 개월 까지의 평균 변연골 소실은 0.52±0.56 mm 였다. 5. 술 후 흡수된 이식재의 양은 0.83±0.38 mm 였고 시간의 흐름에 따른 유의한 차이를 보이지 않았다 (P=0.102). 6. 이식재의 흡수량은 임플란트 식립 시기나 이식재의 입자 크기에 따른 유의할만한 차이를 보이지 않았다 (P=0.644).

이상의 결과를 종합해 볼 때, Osteon®을 상악동 거상술에 적용할 경우, 임상적 및 방사선학적으로 예견성있게 임플란트의 초기 안정성을 유지할 수 있다. 아울러 상악동 거상술 후 감염 등과 같은 합병증이 한 건도 발생하지 않았다는 점에서 단기간의 연구지만 안전하게 쓸 수 있는 재료라고 사료된다.

핵심되는 말: 상악동, 치과 임플란트, 생존율